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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,452	05/05/2006	Hengyuan Lang	34056-US-PCT	9887
75/074 75/90 12/18/2009 NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC. 220 MASSACHUSETTS AVENUE CAMBRIDGE, MA 02139				
EXAMINER				
WILLIS, DOUGLAS M				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
12/18/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,452

Applicant(s)

LANG ET AL.

Examiner

DOUGLAS M. WILLIS

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 5, 12, 20, 21, 23, 29, 34-37 and 54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23 and 37 is/are rejected.
- 7) ☒ Claim(s) 1, 3, 5, 12, 20, 21, 29, 34-36 and 54 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

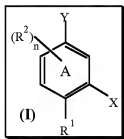
DETAILED ACTION

Status of the Claims / Priority

Claims 1, 3, 5, 12, 20, 21, 23, 29, 34-37 and 54 are pending in the current application. According to the *Amendments to the Claims*, filed October 15, 2009, claims 1 and 37 were amended and claims 2, 4, 6-11, 13-19, 22, 24-28, 30-33, 38-53 and 55-61 were cancelled. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/US2004/023726, filed July 23, 2004, which claims priority under 35 U.S.C. § 119(e) to US Provisional Application No. 60/490,096, filed July 25, 2003.

Status of Restrictions / Election of Species

Applicant's affirmation of the following election, without traverse, in the reply filed on March 5, 2009, is acknowledged: Group II - claims 1, 3, 5, 12, 20, 21, 23, 29, 34-37 and 54, where Y = -L-R³, wherein L = -C(=O)NH- or -NH(C=O)-; and X = -phenyl-, -pyridinyl or -pyrimidinyl; and b) substituted benzene of formula (I) - p. 33, example 1.



The requirement was made FINAL in the *Final Rejection*, mailed on April 14, 2009.

The sections of U.S.C. Title 35 that formed the basis of prior rejections formulated, as well as any references supporting said rejections, that are not included with this Office action, may be found in either the *Non-Final Rejection*, mailed on December 5, 2008, the *Final Rejection*, mailed on April 14, 2009, or the *Non-Final Rejection*, mailed on July 29, 2009. Furthermore, any rejections or objections of record not explicitly addressed herein below, are hereby withdrawn, in light of applicant's arguments and/or the *Amendments to the Claims*, filed

October 15, 2009.

Thus, a fourth Office action and prosecution on the merits of claims 1, 3, 5, 12, 20, 21, 23, 29, 34-37 and 54 is contained within.

New Claim Objections

Claim 1 is objected to because of the following informalities: a) *I* should be replaced with *(I)*, with respect to the structure of formula (I); b) *optionally substituted heterocyclic ring* should be replaced with *optionally substituted heteroaryl ring*, with respect to the amendment for optional substituents; c) *heterocyclic ring* should be replaced with *heteroaryl ring*, with respect to the amendment for optional substituents; d) *substituent* should be replaced with *substituent* at each occurrence, with respect to optional substituents for heterocyclic, heteroaryl and fused bicyclic rings; e) *substituent* should be replaced with *substituent* at each occurrence, with respect to optional substituents for heterocyclic, heteroaryl and fused bicyclic rings; f) *substituted* should be replaced with *substituted*, with respect to optional substituents for aryl rings; and g) *substituents* should be replaced with *substituents*, with respect to optional substituents for aryl rings. Appropriate correction is required.

Claim 3 is objected to because of the following informalities: *III* should be replaced with *(III)*, with respect to the structure of formula (III). Appropriate correction is required.

Claim 5 is objected to because of the following informalities: *V* should be replaced with *(V)*, with respect to the structure of formula (V). Appropriate correction is required.

Claims 12, 20, 21, 29, 34-36 and 54 are objected to because of the following informalities: the claims are dependent upon an objected base claim. Appropriate correction is

required.

New Claim Rejections - 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

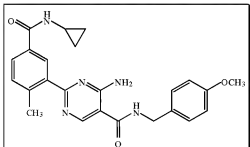
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the limitation *the compound of claim 1, wherein R^{10} is 4-methoxybenzyl*. There is insufficient antecedent basis, in claim 1, for this limitation, with respect to the substituted benzenes of the formula (I). According to claim 1, R^{10} is... $-(CH_2)_r-D-(CH_2)_c-R^{13}$, with respect to the substituted benzenes of the formula (I).

Claim 37 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 recites the limitation *the compound of claim 1: in line 1 of the claim*. There is



insufficient antecedent basis, in claim 1, for this limitation, with respect to *N-(4-methoxybenzyl)-2-[(5-(cyclopropylaminocarbonyl)-2-methylphenyl)]-4-aminopyrimidine-5-carboxamide*, shown to the left.

According to claim 1, R^{10} is... $-(CH_2)_r-D-(CH_2)_c-R^{13}$, with respect to the substituted benzenes of the formula (I).

Allowable Subject Matter

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, AU 1624